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In the Supreme Court of the United States

OCTOBER TERM, 1956

No. 1026

V. E. IRONS, INC., AND V. E. IRONS, PETITIONERS

v.

UNITED STATES OF AMERICA

ON PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE FIRST CIRCUIT

BRIEF FOR THE UNITED STATES IN OPPOSITION

OPINION BELOW

The opinion of the Court of Appeals (Pet. App. 1a–20a) is not yet reported.

JURISDICTION

The judgment of the Court of Appeals was entered on April 24, 1957 (Pet. App. 22a). The petition for a writ of certiorari was filed on May 23, 1957. The jurisdiction of this Court is invoked under 28 U. S. C. 1254 (1).

QUESTIONS PRESENTED

1. Whether Section 502 (f) (1) of the Federal Food, Drug, and Cosmetic Act is rendered vague and indefinite because oral recommendations and advertising

(not labeling) as to the curative effect of drugs were considered in determining whether products sold as drugs bore adequate statements of intended use.

2. Whether wilfullness must be established under 18 U. S. C. 2 (b) by virtue of the fact that the information charged petitioners with "causing" the introduction of misbranded products into interstate commerce.

3. Whether it was reversible error for the trial judge to preclude one of petitioners' expert witnesses from giving his personal opinion as to whether the literature claimed that the drugs would cure specific diseases.

STATUTES AND REGULATION INVOLVED

Section 201 of the Federal Food, Drug, and Cosmetic Act, 52 Stat. 1040, 21 U. S. C. 321, provides in pertinent part:

> For the purposes of this Act—
>
> * * * * *
>
> (g) The term "drug" means * * * (2) articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals; * * *
>
> * * * * *
>
> (k) The term "label" means a display of written, printed, or graphic matter upon the immediate container of any article; * * *
>
> * * * * *
>
> (m) The term "labeling" means all labels and other written, printed, or graphic matter (1) upon any article or any of its containers or wrappers, or (2) accompanying such article.
>
> * * * * *

Section 301, 52 Stat. 1042, 21 U. S. C. 331, provides in pertinent part:

> The following acts and the causing thereof are hereby prohibited:
>
> (a) The introduction or delivery for introduction into interstate commerce of any * * * drug * * * that is * * * misbranded.
>
> * * * * * *

Section 502, 52 Stat. 1050, 21 U. S. C. 352, provides in pertinent part:

> A drug * * * shall be deemed to be misbranded—
>
> (a) If its labeling is false or misleading in any particular.
>
> * * * * * *
>
> (f) Unless its labeling bears (1) adequate directions for use; * * *.
>
> * * * * * *

21 C. F. R. § 1.106 provides in pertinent part:

> *Drugs and devices; directions for use—*
>
> (a) *Adequate directions for use.* "Adequate directions for use" means directions under which the layman can use a drug or device safely and for the purposes for which it is intended. Directions for use may be inadequate because (among other reasons) by omission, in whole or in part, or incorrect specification of:
>
> (1) Statements of all conditions, purposes, or uses for which such drug or device is intended, including conditions, purposes, or uses for which it is prescribed, recommended, or suggested in its oral, written, printed, or graphic advertising, and conditions, purposes, or uses for which the drug or device is commonly used; * * *.
>
> * * * * * *

18 U. S. C. 2 provides in pertinent part:

§2. Principals.

* * * * *

(b) Whoever willfully causes an act to be done which if directly performed by him or another would be an offense against the United States, is punishable as a principal.

STATEMENT

Following a jury trial held in the United States District Court for the District of Massachusetts, petitioners were convicted under a six-count information charging that they had caused misbranded products to be introduced into interstate commerce in violation of the Federal Food, Drug, and Cosmetic Act, 52 Stat. 1040, as amended, 21 U. S. C. 301, *et seq.* Count I charged the introduction into interstate commerce on or about December 16, 1952, of Vit-Ra-Tox No. 21 A and B ("A NATURAL FOOD *with green* life") in violation of Section 403 (j) of the Act, and the regulations promulgated thereunder, in that, although this product was represented on the container as a food for special dietary uses because of its vitamin and mineral content, its label failed to contain required information concerning its vitamin and mineral properties (R. 5–8). Counts II–VI charged that petitioners caused the introduction of misbranded drugs (varieties of Vit-Ra-Tox) into interstate commerce on various occasions in 1952 and 1953, in that the labeling of said drugs was false and misleading in violation of Section 502 (a) of the Act (*supra,* p. 3) and failed to bear adequate direc-

tions for use in violation of Section 502 (f) (1) of the Act (*supra*, p. 3) (R. 8–21).

On October 22, 1956, petitioner V. E. Irons was sentenced to imprisonment for one year on each of the six counts to run concurrently (R. 733). The corporate petitioner was fined $1,000 on each count of the information (R. 734). In an opinion by Chief Judge Magruder, the Court of Appeals for the First Circuit unanimously affirmed the convictions (Pet. App. 1a–20a).

The evidence adduced at the trial may be summarized as follows:

Petitioners distributed various varieties of Vit-Ra-Tox and literature relating to these products (Gov. Ex. 26; R. 149, 783–822, 802–810) to distributors and salesmen in various sections of the country who then retailed these products to customers directly in their homes or offices. These distributors were recruited from customers, acquaintances, and through newspaper advertisements (R. 33–42, 76–80, 134–143, 147–156, 386–387; Gov. Ex. 26; R. 149, 783–821, 814–820).

Petitioner Irons, the president and treasurer of the corporate petitioner (R. 26–27), decided on the physical composition of Vit-Ra-Tox and prepared all the literature relating to the product (R. 382–385). This literature consisted of pamphlets, newsletters, package inserts, letters to customers, and leaflets (R. 735–981, 1007–1008, 1027).

The theme underlying this mass of material was that all human ailments and diseases may be traced to nutritive deficiencies; that nearly everyone is suffering from malnutrition; and that Vit-Ra-Tox would

ameliorate and cure these various diseases (*e. g.*, Gov. Ex. 27; R. 148–149, 833–902, 851). In a pamphlet entitled WHAT PRICE REFINEMENT, sold to salesmen to be left with prospective customers (Gov. Ex. 4; R. 40, 58, 735–740, 737), a Dr. Sutherland is quoted approvingly for the statement that:

> At the present time many conditions are considered as essentially deficiency diseases and are associated in one's thought with the classical Beri-Beri, Pellagra, Rickets and Scurvy. Such conditions are Infantile Scorbutus, Morasmus, Dentition Difficulties and Imperfect Teeth in Children and Adults, Dyspepsias, Indigestions, Diarrhoeas and Constipation, Obesity, Inability to Nurse Children, Diabetes, Neuroses, Infantile Paralysis, Certain Myalgias or "Rheumatism," Dementia Praecox, and even Tuberculosis and Cancer.

Certain of the literature specifically extolled the curative effect of Vit-Ra-Tox or of the ingredients contained therein. Thus, Vit-Ra-Tox No. 21, containing a mixture of dried extracted juices of cereal grasses, was claimed as a cure for arthritis (Gov. Exs. 14 and 15; R. 73, 763–770). Garlic, an ingredient of Vit-Ra-Tox No. 21 B, was said in the literature to be comparable to penicillin and had been customarily used for diphtheria, respiratory infections, boils, carbuncles, and suppurating sores (R. 268–269; Gov. Ex. 9; R. 58, 749–752). Bentonite, contained in Vit-Ra-Tox No. 16, was indirectly recommended for cleansing the brain, nervous system, blood, muscles, and tissues of the body (R. 319; Gov. Ex. 26; R. 149, 783–822, 802–806).

To establish that these and other claims contained in the literature distributed by petitioners were false, the Government called several experts (including Dr. Frederick J. Stare, Professor of Nutrition and Head of the Department at Harvard Medical School, and Dr. Leonard A. Maynard, Professor of Nutrition, Emeritus, Cornell University, formerly Director of its School for Nutrition), who testified that Vit-Ra-Tox or its ingredients would not cure the various diseases referred to in the literature (R. 105–131, 198–209, 234–244, 260–274, 296–307, 315–328). Several witnesses, including two dentists and three physicians, testified as experts for petitioners (R. 397–458, 519–544, 586–595, 607–636, 658–669).

As to the charge of misbranding, under Counts II–VI, in that the labeling of the drugs failed to contain adequate directions for use, the jury was instructed to consider all claims, whether contained in the literature or in oral representations of petitioner Irons and one of the salesmen, if they found that "* * * any [such] claims are made for the cure, prevention or mitigation of disease" (R. 699, 703–704). On the charge of false labeling contained in the same counts, the jury was charged to consider only that portion of the literature it deemed to be "labeling" (R. 699), defined by the trial judge as that literature employed in the sale or use of the product or to promote such sale or use (R. 699).

The oral recommendations made by petitioner Irons occurred during a "talk to distributors" (R. 158) attended by a Food and Drug Inspector in the guise of

a salesman (R. 157). The inspector testified that Irons discussed cancer, female troubles, sexual impotence, and sexual perversion (R. 159). He mentioned a woman whose menstrual difficulties ceased with the taking of Vit-Ra-Tox (R. 159). He noted that "* * * cancer can be cured in three to ten weeks"; that such cure was then being successfully accomplished with potassium salts; and that potassium salt was specified as an ingredient on the label of Vit-Ra-Tox (R. 160). The other oral representation was made by a salesman of Vit-Ra-Tox. One Elmer Struckmeyer testified that he purchased Vit-Ra-Tox No. 21 because he was told it would cure arthritis—a disease from which he suffered (R. 386–389).

ARGUMENT

1. With respect to the construction of the statute, no issue is raised as to Count I of the information. Nor do petitioners challenge that part of Counts II–VI which charges false and misleading labeling—a charge squarely within *Kordel* v. *United States,* 335 U. S. 345. Their attack, in this aspect of the case, is only on that portion of Counts II–VI which charged a violation of Section 502 (f) (1) of the Act (*supra,* p. 3) requiring labeling of drugs to contain directions for use. They argue that, if the section applies to products recommended as treatment for diseases in oral statements and advertising other than labeling, the section is unconstitutionally vague and indefinite (Pet. 5–9).[1]

[1] Oral statements were actually only a minor part of the proof in this case.

A similar argument was recently rejected by the Third Circuit in *United States* v. *Adolphus Hohensee, et al.*, Nos. 11,977–11,979, decided on January 29, 1957. This court denied certiorari on May 27, 1957, No. 909, this Term. Further review is equally unwarranted in the instant case.

Under administrative regulation (*supra*, p. 3) and undeviating court decision, all relevant representations—whether labeling or not—may properly be considered to determine the purposes, diseases, and conditions for which a drug is intended. *E. g., Alberty Food Products* v. *United States*, 185 F. 2d 321, 325–326, and 194 F. 2d 463, 464 (C. A. 9); *Colgrove* v. *United States*, 176 F. 2d 614, 615 (C. A. 9), certiorari denied, 338 U. S. 911; *United States* v. *El-O-Pathic Pharmacy*, 192 F. 2d 62, 77 (C. A. 9); *United States* v. *Cruez*, 144 F. Supp. 229 (E. D. Ill.); *United States* v. *3 Cartons, etc.*, 132 F. Supp. 569 (S. D. Cal.); *United States* v. *Vitamin Industries Inc.*, 130 F. Supp. 755, 765 (D. Neb.).

If the rule were otherwise, it would be a simple matter to circumvent Section 502 (f) (1) merely by limiting curative claims to oral representations. There is certainly nothing uncertain in requiring a person to specify directions for use for the various diseases he represents a drug will cure, regardless of the media of expression he chooses for making such representations. "The high purpose of the Act [is] * * * to protect consumers who under present conditions are largely unable to protect themselves in this field. * * *." *Kordel* v. *United States*, 335 U. S. 345, 349; *United States* v. *Sullivan*, 332 U. S. 689; *United*

States v. *Dotterweich*, 320 U. S. 277. Loopholes should not be created by "strained and technical constructions * * *." *Kordel, supra*, at p. 349; *United States* v. *Urbuteit*, 335 U. S. 355, 357–358.

Nor is there any merit to petitioners' further allegation that the oral representations, not being labeling, were not relevant in a prosecution under the Federal Food, Drug, and Cosmetic Act, but that prosecution for their content was solely within the exclusive jurisdiction of the Federal Trade Commission (Pet. 8–9). The truth or falsity of the oral representations and the literature, when considered on the charge of inadequate directions for use, was not in issue. Their consideration was properly limited to whether the labeling bore adequate directions for use for the diseases for which the products were intended. See *Alberty Food Products* v. *United States*, 194 F. 2d 463, 464 (C. A. 9); cf. *Kordel* v. *United States*, 335 U. S. 345, 351.

2. Petitioners contend (Pet. 9–11) that, since each of the six counts charged petitioners with "causing" the entry into interstate commerce of a misbranded product, wilfullness was made an essential element of the offense pursuant to 18 U. S. C. 2 (b), which provides that one who "wilfully" causes an act to be done is liable as a principal. Even on petitioners' theory, the requisite "wilfullness" would relate only to the introduction into interstate commerce, since it is well established that intent is not an essential element of the offense of misbranding under the Federal Food, Drug, and Cosmetic Act. *United States* v. *Dotterweich*, 320 U. S. 277, 285–286; *United States*

v. *Kaadt*, 171 F. 2d 600, 604 (C. A. 7). Since there was no real issue as to the fact that petitioners did intentionally ship their products in interstate commerce, the contention has no substance in relation to the facts of this case.

In any event, petitioners misread 18 U. S. C. 2 (b). It is quite plainly a general statute which, insofar as material, was designed to impose liability for causation where other statutes do not do so. It has no application here, since Section 301 of the Federal Food, Drug, and Cosmetic Act by its own terms specifically prohibits "causing" the introduction of misbranded products in interstate commerce.

3. Almost at the end of the direct examination of a Dr. Philip Norman, one of the physicians called by petitioners as an expert witness, the trial judge, upon the Government's objection, precluded him from answering questions as to whether, from a reading of petitioners' literature, he had "* * * an opinion as to whether or not the defendants are claiming cures for specific diseases" (R. 455–456). During Dr. Norman's lengthy direct testimony prior to said question, he had, among other things, given his opinion that the theories of nutrition set out in petitioners' literature were true, and had attributed indigestion, anemia, nervousness, varicose veins, hay fever, asthma, tuberculosis, and cancer to improper nutrition (R. 397–455, 422–427). The court agreed with the Government that the witness was not qualified, but excluded the question primarily on the ground that "it is a factual question for the jury" (R. 456).

The ruling was clearly correct. "The Federal Food, Drug, and Cosmetic Act was not made for experts * * * [but] is to protect the public, the vast multitude which includes the ignorant, the unthinking, and the credulous who, when making a purchase, do not stop to analyze." *United States* v. *62 Packages, etc.*, 48 F. Supp. 878, 887 (W. D. Wis.), affirmed, 142 F. 2d 107 (C. A. 7), certiorari denied, 323 U. S. 731; *Kordel* v. *United States*, 335 U. S. 345, 349; *United States* v. *Urbuteit*, 335 U. S. 355, 357–358; cf. *Federal Trade Commission* v. *Standard Education Society*, 302 U. S. 112, 116. It was for the jury to say whether petitioners were representing to the public that their product would cure disease.

Petitioners' reliance on *United States* v. *38 Dozen Bottles, Etc.*, 114 F. Supp. 461 (D. Minn.), is misplaced. In that case, one of the Government's experts, a specialist in internal medicine, did not disclose his own opinion of the advertisement, but his opinion of the impression that ulcer patients might receive (114 F. Supp. at 463). The other Government experts in that case were noted advertising and marketing specialists who had exhaustingly analyzed the advertisement and interviewed 200 persons concerning their impressions of the advertisement (114 F. Supp. at 462–463). In the instant case, petitioners' witness was a practicing physician (R. 398), who was asked merely to give his personal opinion of what the representations would mean to him.

CONCLUSION

For the foregoing reasons, it is respectfully submitted that the petition for a writ of certiorari should be denied.

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JUNE 1957.

U. S. GOVERNMENT PRINTING OFFICE: 1957